EXHIBIT 65

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
Telephone: (612) 758-7115
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Rec'd 11/19/10

November 17, 2010

Gary R. Maharaj
President and CEO
Arizant Inc.
10393 W. 70th Street
Eden Prairie, Minnesota 55344

Dear Mr. Maharaj:

We enclose a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises at Eden Prairie, MN, on November 30, 2009-January 6, 2010, by Investigator Jessica L. Johnson of the Food and Drug Administration (FDA). This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to regulated industry. Releasing the EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting and possibly obtaining additional information under FOIA.

If there is any question about the released information, feel free to contact me at the address indicated on the letterhead.

We received your letter dated January 20, 2010, which replied to the FDA 483 Inspectional Observations issued on January 6, 2010, at the conclusion of an inspection of your firm. Your letter has been made a part of the Minneapolis District's permanent file for your firm. The implementation and effectiveness of your corrective actions will be evaluated during the next inspection.

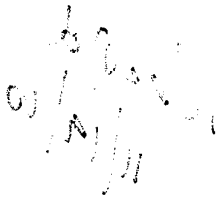
Sincerely,

Catherine Leonard for

Gerald J. Berg
Director
Minneapolis District

TGP/ccl

Enclosure: EIR, 11/30/09-1/6/10



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SUMMARY

Arizant Inc. is a manufacturer of forced air patient warming systems used in hospitals and medical centers to prevent hypothermia during and after surgical procedures. This limited/"for cause" inspection was conducted to investigate a complaint regarding potential microbial air contamination, the firm's MDR procedures, and justification for not reporting adverse events. The assignment from CDRH is Attachment 1. Compliance Program 7382.845G was used for guidance during this inspection.

The previous inspection on 06/09-11/09 did not find any significant quality system deficiencies. No observations were made, and no samples were collected.

The current inspection covered all Arizant products and resulted in the issuance of a 5-item FDA 483 citing deficiencies in the areas of quality systems, Medical Device Reporting (MDR), and Corrections and Removals. Most of the issues deal with complaint handling and subsequently MDR reporting. The cites include failure to file MDR reports for both serious injuries and malfunctions (**Observations 1 & 2**), inadequate MDR procedures (**Observations 3**), failure to report a correction or removal action to FDA (**Observation 4**), and failure to document complaint investigations (**Observation 5**).

Arizant management annotated the 483 as follows: Obs # 1 & 2- "Promise to correct within 15 days". The firm plans to file MDRs for the complaints cited in Observations 1 & 2. Obs # 3 & 5 were annotated as "Reported corrected, not verified". The firm has drafted a new revision of the Adverse Event/Injury Reporting procedure and has implemented a new complaint documentation system. Lastly, Obs # 4 was annotated as "Corrected, and verified". The 21 CFR 806 required information for a Correction and Removal was provided by the firm. This information has subsequently been forwarded to Kristy Zuroski, Minneapolis District Recall Coordinator. The firm has opened a CAPA to address all observations noted on the 483. They also plan to respond in writing to the district within 15 days of the close-out meeting. No samples were collected, and no refusals were encountered during this inspection.

ADMINISTRATIVE DATA

Inspected firm:	Arizant Inc
Location:	10353 W 70th St Eden Prairie, MN 55344
Phone:	952-941-8866
FAX:	
Mailing address:	10393 W 70th St Eden Prairie, MN 55344
Dates of inspection:	11/30/2009, 12/2/2009, 12/3/2009, 12/8/2009, 12/18/2009, 12/29/2009, 1/6/2010
Days in the facility:	7
Participants:	Jessica L. Johnson, Investigator

On 11/30/2009, I displayed my credentials and issued an FDA-482, Notice of Inspection, to Mr. David A. Westlin, Chief Compliance Officer/Senior Director of Regulatory Affairs. Mr. Westlin was the most responsible individual available at the start of the inspection.

The FDA-483 was issued to Mr. Gary R. Maharaj, President and CEO, who was the most responsible individual present during the close-out meeting.

HISTORY

Arizant was incorporated in 2003 after splitting from Augustine Medical. The Arizant campus in Eden Prairie contains 3 buildings including manufacturing facilities. The firm also has a warehouse in Shakopee, MN from which finished goods are shipped. The firm has approximately 250 employees, and the hours of operation are 8:00 – 5:00pm.

Arizant has conducted the following recalls since 2005:

Recall Number	Class	Date	Product & Reason for Recall
Z-0855-2005	2	03/11/05	Bair Hugger Blanket- seal separation upon inflation
Z-1183/4-2007	2	8/10/2007	Ranger standard flow IV Blood/Fluid warming set- partial or incomplete seal on pouch. Sterility not guaranteed.
Not yet numbered	2	12/07/09	All products that use Electri-Cord AC power cords- power cord failures, potential for electric shock, delay in setup and therapy, interruption of therapy, device failures, and fire.

The top official at Arizant Inc. is Gary R. Maharaj, President and CEO, 10353 W 70th St. Eden Prairie, MN 55344

INTERSTATE COMMERCE/JURISDICTION

Arizant Healthcare manufactures Class II forced-air patient warming systems used to maintain patient normothermia during and after surgical procedures. The products include the Bair Hugger warming blankets, Bair Paws patient adjustable warming system, and Ranger blood and fluid warming systems.

The Bair Hugger product line makes up approximately 80% of sales. For a comprehensive product catalog, see Exhibit 1.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 11/30/06, I displayed my credentials and issued an FDA-482, Notice of Inspection to Mr. David A. Westlin, Chief Compliance Officer/Senior Director of Regulatory Affairs. Mr. Westlin was the most responsible individual onsite at the onset of the inspection. See Exhibit 2 for Arizant organizational charts.

Gary R. Maharaj, President and CEO. Mr. Maharaj is the most responsible individual at Arizant Inc. He provided a brief history of the contamination issue that was discussed during the inspection. He was also present for the close-out meeting.

David A. Westlin, Chief Compliance Officer/Senior Director of Regulatory Affairs. Mr. Westlin provided the majority of the information found in this report, and he was present throughout the entire inspection.

Mark Burville, Regulatory Affairs Manager. On 12/29/09, Mr. Burville provided a description of the firm's new complaint documentation system that is currently being implemented as well as CAPA information. Mr. Burville was also present during the close-out meeting.

Inspectional Coverage

This inspection was conducted to investigate a complaint alleging that the Bair Hugger patient warming unit has the potential to release microbial particles into the surrounding environment and contaminate the air. In addition, the MAUDE database revealed a total of 19 adverse event reports only 2 of which were filed by the manufacturer. Information regarding the firm's justification for not reporting the remaining events was gathered.

The inspection began with a discussion about contamination concerns regarding the Bair Hugger temperature warming unit. The firm does not have a procedure concerning environmental and contamination controls specific to microbial contamination. The warming unit has a 0.2 µm HEPA filter which is in place as a secondary safeguard against contamination after the hospital/medical clinic's air filtration systems. The warming unit is attached to a disposable, single-use, latex-free blanket via a hose. These blankets come in various models for both adult and pediatric patients. A limited number of blanket models are offered for sale as both sterile and non-sterile. Arizant's contract sterilizer is Steris in Coon Rapids, MN.

Mr. Westlin pointed out page 10 of the Bair Hugger Temperature Management Unit Model 505 Operator's Manual (Exhibit 3, pg 11) where general maintenance instruction are provided. For cabinet cleaning, the manual states, "Use a damp soft cloth and a mild detergent to clean the unit cabinet. Dry with a separate soft cloth." These are the only cleaning instructions provided with the units.

The firm has not initiated any CAPAs in response to contamination issues as no such issues have been brought to the firm's attention. A review of the complaint database from January 2006 – present did not reveal any issues with microbial air contamination as a result of using the patient warming units. It should be noted that Arizant uses a Cause Code "BG27 Contamination" (See Exhibit 4 for complaint code key) to indicate debris found within the blanket packaging. The explanation of the usage of this complaint code was provided by Dave Westlin. A query of complaints coded as BG27 did indicate it is used to code events involving foreign objects found within the blanket packaging. No microbial air contamination complaints were uncovered during the inspection. Multiple, independently-conducted studies were provided by the firm in response to the contamination inquiry. Collectively, the studies conclude the forced-air warming system does not increase bacterial contamination in the operating room. The provided studies include:

"Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?" B. Moretti, et al. University General Hospital, Bari, Italy. 4 June 2009. (Exhibit 6)

"The "six sigma approach" to the operating room environment and infection." R. H. Thiele, et al. University of Virginia Health Sciences Center, Charlottesville, VA. Best Practice & Research Clinical Anaesthesiology, Vol. 22, No. 3, pp. 537-552, 2008. (Exhibit 7)

"The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?". J KC Huang, et al. Queen Elizabeth Hospital, King's Lynn, UK. *Critical Care* 2003, 7:R13-R16. 4 March 2003. (Exhibit 8)

"Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room". R. S. Zink & P. A. Iaizzo. University of Minnesota, Minneapolis, MN. ANESTHESIA & ANALGESIA, Vol. 76, No. 1, January 1993. (Exhibit 9)

"Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room". A.C. Hall, MB, MS; T. Teenier, DDS. University of Texas Southwestern Medical Center, Dallas, TX. Poster Presentation, PGA, 9 December 1991. (Exhibit 10)

"Convection warmers- a possible source of contamination in laminar airflow operating theatres?". N Tumia and G. P. Ashcroft. Aberdeen University Medical School, Foresterhill, Aberdeen, Scotland. Journal of Hospital Infection (2002) 52: 171-174. (Exhibit 11)

"Forced-Air Warmer Did Not Increase the Risk of Contamination Caused by Interference of Clean Airflow". H Miyazaki, MD, et al. Anesthesiology 2007; 107: A1594. (Exhibit 12)

Any highlighting noted on the above listed studies was performed by the firm prior to my possession of the documents.

At the onset of the investigation, I collected an electronic copy of all complaints involving the Bair Hugger product from January 2006 - present; Dave Westlin provided the disk which contains a Microsoft Excel Worksheet with the Bair Hugger complaint data. The original disk, which was placed in a paper bag and officially sealed, is Exhibit 13. Exhibits 4 - 5 are the complaint and failure code keys used by the firm.

Using a working copy of the electronic data, I used a number of computer aided techniques to determine which hard file copies to review during the inspection. For example, problem code I99 indicates an 'injury report', and by querying for this code I was able to identify injury related complaints. Also, I queried for specific events which had been reported as MDRs by user facilities to see if the firm had been informed of the incident. No conclusions were drawn from the electronic data alone. Any and all observations are based on review of the hard copy complaints including accompanying documentation provided by the firm.

On 12/02/09, an electronic copy of all Bair Paws and Ranger complaints was provided by Dave Westlin. The same techniques as stated above were used on this electronic data, and the disk is Exhibit 14.

RECALL PROCEDURES

SOP 140201, Recall and Advisory Notice Procedure, Rev E was provided by the firm (Exhibit 15). On 12/7/2009, the firm initiated a recall due to power cord failures. The 21 CFR 806 information was sent to Kristy Zuroski, Minneapolis District Recall Coordinator. The power cord failures have the potential to cause "electric shock, delay in setup and therapy, interruption of therapy, device failures, and fires". A copy of the recall letter sent to the district as well as the "Urgent: Medical Device Power Cord Recall" letter are attached as Exhibits 16 & 17 respectively.
Additional information regarding recalls may be found under **Observation 4.**

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, the following adverse event was not filed as an MDR:

CALL 63505 dated 04/13/06 states, "Female pt sustained 2nd degree burn to breasts and surrounding soft tissue after approx 1 hr knee scope porcedure [*sic*] in the OR with Bair Paws 84001 or 84201 OR gown and 505 warming unit (S/N 69412)." The patient was subsequently treated in the ER.

Annotation: Promised to correct within 15 days.

Reference: 21 CFR 803.50(a)(1)

Supporting Evidence and Relevance:

The coverage of MDRs began by reviewing the firm's SOP 140500 Adverse Event/Injury Reporting, Rev G (Exhibit 18). The procedure states that the injury review team will "determine if this is a reportable incident under the FDA," (page 3). I asked Mr. Westlin how that determination is made,

and he provided me with a letter addressed to the U.S. Food and Drug Administration dated May 7, 1992 (Exhibit 19). The letter outlines burn severity from first to third degree. Arizant's policy has been to report only 3rd degree burns.

CALL 63505 (Exhibit 20) was received on 04/13/06 and involved a patient who sustained 2nd degree burns; the patient was subsequently moved from the surgery center to the ER where the burns were treated. An Initial Adverse Event/Injury Report form, AMI148, was completed by an Arizant customer service rep (page 2). In addition to the hospital reporting the incident, on May 18, 2006 the patient personally contacted Arizant via the website contact feature. The patient stated she 'ended with third degree burn on my left breast" and inquired about the product (page 4).

[NOTE: During the inspection, I double-checked my interpretation of the regulation with Linda Hoffman, Consumer Safety Officer, FDA/CDRH/Division of Surveillance Systems. She confirmed that this event should have been reported.]

Discussion with Management:

During the close-out meeting, the firm stated they would file an MDR for this event within the next 15 days. We also discussed the Adverse Event/Injury Reporting procedure and the letter used to determine MDR reportability (See **Observation 3** for detailed discussion).

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the following malfunction complaints were not filed as MDRs:

Complaint	Reported Event
CALL 73378 dated 07/30/07	"Heater in unit is not functioning, does not heat" The patient exhibited disseminated intravascular coagulation (DIC) as a result of lowered body temperature which led to excessive bleeding.
CALL 76774 dated 01/02/08	Physician stated the warming unit was found to be operating improperly resulting in two burn incidents. The event was reported confirmed by the biomed group.
CALL 92646/92618 dated 08/20/09	Pt injury on or about 8/17 was reported by a healthcare professional when the warming unit hose partially separated from the blanket. Warming continued and "pt sustained redness or a burn".
CALL 66624 dated 09/14/06	Unit caught fire while in use on the patient's bed. The device was immediately unplugged and removed from the stretcher.

CALL 81669 dated 07/15/08 involved. Unit caught fire in the OR down at the power cord. No patient was

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Annotation: Promised to correct within 15 days.

Reference: 21 CFR 803.50(a)(2)

Supporting Evidence and Relevance:

The firm's current Adverse Event procedure does not take into account malfunctions that would be likely to cause or contribute to death or serious injury. As mentioned above, see **Observation 3** for a detailed discussion on the Adverse Event/Injury Reporting SOP.

CALL 73378 (Exhibit 21) dated 07/30/07 states, "Bair hugger applied during abdominal aortic aneuysm surgery. Two hours into procedure patient bleeding was noted, patient temperature had dropped to 32.4 and bair hugger devive found to be providing room temp (cool) air" (page 1). The user facility filed a MedWatch report (1600450000-2007-8001) (page 4-5). The MedWatch report states, "Heater in unit is not functioning, does not heat. The rest of the unit appears functional. Taken out of service." As a result, the patient's hypothermic state induced disseminated intravascular coagulation which was indicated by bleeding at the mouth, and medical intervention was required to increase the patient's body temperature. Post-operative warming therapy was applied for 8 hours at which point the patient became normothermic. The implicated device is S/N J55316. This incident was not filed as an MDR nor was there any evidence of a documented evaluation of reportability.

CALL 76774 (Exhibit 22) dated 01/02/08 alleges "Burns noted after surgery". A follow-up conversation with the doctor was held on 03/04/08. During this conversation it was noted that, "...they had two burn incidents. One involved a pediatric patient that had a burn a couple blisters. She said the patient's parents made a big deal about it initially, but the blisters resolved and the patient is fine. The other involved an infant who was sent to the local Children's Hospital… Dr. Foley said the warming unit was found to be operating improperly. She said she heard that when they turned it down the temperature actually went up. She said it had been confirmed by the biomed group." (page 15). The user facility filed a MedWatch report (490063-2007-0001) (page 3-4). The Medwatch report states, "Post-operatively pt noted to have burns on 17% of body; distribution consistent with Bair Hugger blanket contact." An Innova Patient Temperature Record (page 5) shows the functioning of the device; it appears the temperature increased once the device was shut off. This malfunction could have potentially caused serious injury if the burns on the patient were not noticed and the blanket removed. The incident was not reported by the firm because the narrative indicated the patient's blisters healed on their own. Because the burns were not stated to be 3rd degree, no MDR was filed. The unit's part number is 50201, and the serial number is A06219.

CALL 92646 (Exhibit 23) dated 08/20/09 states, "Dennis Farine relayed a report from Dawna Wilsey, Education Manager of a pt injury on or about 8/17 when the hose partially separated from the blanket hose card. Warming continued and pt sustained redness or a burn. Wisley had no information concerning the pt, procedure, blanket, or unit being used." (page 1). A MedWatch report (0533020000-2009-8014) was filed by the user facility (page 2-3). This incident was also captured in CALL 92618 (page 10) which said, "a baby was burned". Had the hose remained separated from the blanket and warming continued, serious injury could have ensued.

CALL 66624 (Exhibit 24) dated 09/14/06 involved a unit (S/N 08364) that was returned after catching fire while in use. A voluntary MedWatch report (4200070000-2006-8028) was filed and provided to the manufacturer. The report states, "A warming system was in use and hanging on patient's bed rail and the staff smelled something burning. Smoke began rising from the device and then flames were noted to be coming from the device. The device was immediately unplugged and removed from the stretcher. The flames went out spontaneously and the extinguisher was not used." (page 13-14). FDA requested additional information regarding this incidence on two occasions. The firm provided two written responses (pages 15-16, 46-47).

This fire occurred while the unit was positioned on the patient's bed. If the power cord hadn't been removed from the wall in a timely fashion or if the flames hadn't spontaneously extinguished, both the patient and care-giving staff could have been seriously injured. The firm did not file an MDR because no patient was injured. (See **Observation 4** for additional information regarding this event).

CALL 81669 (Exhibit 25) dated 07/15/08 states, "unit "caught fire" in OR down at the power cord. Biomed say's facility is going to file a incident report. NO incident involving a patient. Customer will call Geoffrey Macdonald to get a replacement model bair hugger." (page 1). The serial number for the device is D31404; no additional follow-up information was available.

This malfunction could cause or contribute to death or serious injury if the fire would have spread. Those at risk include both the patient and the hospital staff. The firm did not file an MDR because the patient was not injured. No additional documentation was available regarding this incident.

Discussion with Management:

During the close-out meeting on 01/06/10, the firm stated they would file MDRs for these device malfunction events within 15 days. Multiple changes have been made to the Adverse Event/Injury Reporting SOP including evaluation for regulatory reporting requirements for device malfunctions. See **Observation 3** below for a detailed discussion.

OBSERVATION 3

The written MDR Procedure does not include an internal system which provides for the timely and effective evaluation of events that may be subject to medical device reporting requirements.

Specifically, Procedure No. 140500, Adverse Event/Injury Reporting, Rev G does not provide guidance for determining when an event meets the criteria for reporting. Effective evaluation of each injury and malfunction complaint has not been implemented (as is demonstrated by Observations 1 &2).

In addition, there is no documented evaluation to determine the reportability for the following injury complaints:

Complaint	Reported Event
CALL 90142 dated 05/22/09	21 mo male child received 2nd - 3rd degree burns on left ear. Arizant manager stated in July 2009 that the "staff concluded that the incident was not due to the warmer or Bair Hugger blanket".
CALL 79475 dated 04/16/08	Reported 2nd - 3rd degree burn to a pt. during a two hour procedure. In August 2008, the injury was said to have been 1st degree burns.
CALL 95129 dated 11/09/09	11 incidents of pt burns to the mid back during ENT surgeries. "Blistering, followed by sloughing of the surface layers occured 12+ hours later". Current patient conditions unknown.
CALL 85323 dated 11/25/08	Patient burned on lateral thighs during abdominoplasty and breast aug. In Feburary 2009, Arizant was made aware the blanket did not cause the burns via email.

Annotation: Reported corrected, not verified.

Reference: 21 CFR 803.17(a)(1)

Supporting Evidence and Relevance:

As is evident in **Observations 1 & 2**, Procedure No. 140500, Adverse Event/Injury Reporting, Rev G (Exhibit 18) does not allow for adequate evaluation of injury/malfunction complaints received by the firm. Those complaints already mentioned in addition to the ones outlined above demonstrate the procedure's ineffectiveness.

The letter (Exhibit 19) dated May 7, 1992 addressed to the Food and Drug Administration is currently being used by the firm as guidance for reportability. The letter states, "We have relied on the standard classification of thermal skin injuries (burns) to determine if a given injury is serious. 1st degree: Reddening of the skin. 2nd degree: Blistering of the skin. Partial thickness injury. 3rd degree: Full thickness skin injury and skin loss. In general, all partial thickness skin injuries (1st

and 2nd degree) heal without intensive therapy, without scarring and without any permanent impairment. Full thickness skin loss (3rd degree) will require more intensive therapy of skin grafting. We therefore elected to report only 3rd degree full thickness injuries to the FDA via MDR." (page 1). As these generalizations cannot be applied to every situation, effective evaluation for each injury complaint has not been established. In addition, complaints involving malfunctions are not evaluated to determine if the event meets the criteria for reporting.

The following complaints (with corresponding Exhibit numbers) are examples of adverse events that have no documented evidence of MDR evaluation.

Call	Exhibit
90142	26
79475	27
95129	28
85323	29

In each case, a serious injury was reported, and the firm gathered additional information over an extended period of time. In 3 of the cases, the hospital/clinic confirmed the injury was not due to the Arizant product or the injury was less severe than initially reported. Had the firm not been able to conclude the incident was not due to an Arizant product, the lack of MDR evaluation/reporting would cause for untimely reports.

Discussion with Management:

A new revision of Procedure No. 140500 Adverse Events/Injury Reporting has been drafted to include more detailed reporting guidelines including broader language adopted from the regulations. (A copy of the new revision was not obtained at the time of close-out because it was still in draft form and not an approved quality document. The firm stated they would provide the approved SOP in their written response to the district within 15 days of the close-out.) A new form is also being implemented to document MDR evaluation activities for each injury/malfunction complaint. The form will capture whether the firm believes an event should be reported and if not, the justification for not reporting.

We also discussed the difficulty of obtaining information from hospitals and medical facilities. The firm raised concern about the reliability of some reported events especially those from biomedical engineering departments which do not have interaction with the patients. We addressed the need to evaluate all provided information for regulatory reportability in a timely manner. If pertinent information is made available to the firm at a later date, a supplementary report may be submitted.

OBSERVATION 4

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, in January 2007, a Service Bulletin with enclosed "Blower Inspection Model 850 Warming Unit" instructions was sent to Arizant Bair Paws Model 850 customers. The service bulletin asked users to inspect their Model 850 Bair Paws units for the sagging heater coil and subsequently attach the provided 'Inspected' sticker on each unit. The bulletin also advised customers to discontinue use of the units found to have continuously running motors and return these units to Arizant. Arizant would then send the consignee a replacement unit.

Annotation: Corrected and verified.

Reference: 21 CFR 806.10(a)(1)

Supporting Evidence and Relevance:

Consumer complaint 66624 (Exhibit 24) was received regarding a Bair Paws Model 850 warming unit which caught fire while positioned on a patient's bed. The complaint investigation revealed a triple fault causing the motor to overheat due in part to a sagging heater coil that may come in contact with the unit's thermostat. As a result of this investigation, a service bulletin was issued to all (approximately 650) consignees of the affected model (approximately 9,000 units in total). The consignee list is shown in Exhibit 30. The Service Bulletin asked users to inspect their Model 850 Bair Paws units for the sagging heater coil and subsequently attach the provided 'Inspected' sticker on each unit. The service bulletin and the Blower Instructions are shown in Exhibits 31 & 32, respectively. The bulletin also advised customers to discontinue use of the units found to have continuously running motors and return these units to Arizant. Arizant would then send the consignee a replacement unit. A correction was made in order to reduce the risk to health; this correction was not reported to the FDA.

Discussion with Management:

Mr. Westlin stated that approximately 10 years ago the firm initiated a Field Action which was not reported to FDA. The field action was similar to this Model 850 service bulletin. He said the firm had been told they handled the field action correctly, and because this was a similar situation, they chose not to report the Model 850 correction. The 21 CFR 806 required information was provided by the firm at the close-out meeting. A copy of the Recommendation for Recall Classification Memo is shown in Attachment 4. This memo including the 21 CFR 806 information has been forwarded to Kristy Zuroski, Minneapolis District Recall Coordinator.

OBSERVATION 5

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically, customer complaint investigations or justification for not investigating are not documented for the following complaints:

CALL	Date	Reported Event
85743	12/12/08	Burned controller- "Says the controller is all carboned up on the bottom side. The carbon is due to high heat."
89918	05/13/09	Exchange, not heating, no fault code- "Elbow sensor defective".
90025	05/19/09	Kink in cassette caused leak
91168	06/30/09	Exchange, fan runs continuously
91451	07/10/09	"Exchange, burn smell after turn on, then smoke"

The information provided for each reported event is limited.

Annotation: Reported corrected, not verified.

Reference: 21 CFR 820.198(c)

Supporting Evidence and Relevance:

Procedure No. 140400, Complaint Management, Rev L (Exhibit 33) section 5.2 states that the service department will "Determine the need and extent of Failure Analysis to be performed. Document all findings on the failure analysis form, service form, and scrap form or in DHR…Document the completed repair. When applicable, Failure Analysis findings and Complaint Resolution will be entered into the complaint database." (page 4). This practice was not seen in the following examples:

CALL 85743 (Exhibit 34) dated 12/12/08 states, "Says the controller is all carboned up on the bottom side. The carbon is due to high heat…Fluid ingress through handle screw." No additional

documentation showing the failure investigation was available including by whom and when the analysis was performed.

CALL 89918 (Exhibit 35) dated 05/13/09 states, "exchange, not heating, no fault code…Elbow sensor defective…power cord, bott. Enclosure, know, pole clamp, bumper iv pole, filter, interface, sensor assy, gaskets, control board, hose assy." The failure analysis has not been documented.

CALL 90025 (Exhibit 36) dated 05/19/09 states, "Report that a 242 cassette was kinked to a piont [*sic*] that caused leaking during the priming process. Cassette retrived [*sic*] and being sent to AHI for review…" A letter was sent to the complainant saying the device failure was the "result of a special cause". However, there is no failure investigation documented for the kinked cassette.

CALL 91168 (Exhibit 37) dated 06/30/09 states, "exchange, fan runs continuously…installed new power cord, warning label, control board, filter, gasket kits, main plate gasket, anti hose label, hose assy, clip assy."

CALL 91451 (Exhibit 38) dated 07/10/09 states, "exchange, burn smell after turn on, then smoke…Fluid ingression on alaram [*sic*] board, most likely through handle of the unit." The investigation performed in order to come to the conclusion that fluid ingress caused the smoke has not been documented.

Discussion with Management:

Mr. Westlin stated that prior to my arrival at the firm, they had identified weaknesses in their complaint handling system and had recently started to implement a new complaint documentation system. Mr. Burville explained that complaints are now being entered as Corrective Action Request Documents (CARD). All CARDS created for complaints are reviewed by the quality assurance department and assigned to a quality engineer for investigation and follow-up. The following improvements to the complaint handling system will be made: complaints will be assigned risk levels based on severity, complaints will be reviewed by both QA and RA, and root cause categories and subcategories will be used to trend and ID areas of concern. An example of the firm's new Failure Analysis report is shown for CALL 95193 dated 11/11/09 in Exhibit 39, page 2.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the close-out meeting, Mr. Westlin provided a Corrective Action Request Document (CARD) #1247 (Exhibit 40) as the firm's response to the observations noted on the FDA-483. The CARD

includes a Summary of Root Cause Analysis and Initial Corrective Actions for each observation (pages 3-5). The firm's proposed completion date for the corrective action is 01/20/10. Mr. Westlin stated the firm will respond in writing to the district within 15 days of the close-out meeting.

SAMPLES COLLECTED

No samples were collected during this inspection.

EXHIBITS COLLECTED

1. Arizant Product catalog
2. Arizant Organizational Charts (2 pages)
3. Bair Hugger Temperature Management Unit Model 505 Operator's Manual
4. Complaint code key
5. Failure code key
6. *"Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?"* B. Moretti, et al. University General Hospital, Bari, Italy. 4 June 2009
7. *"The "six sigma approach" to the operating room environment and infection."* R. H. Thiele, et al. University of Virginia Health Sciences Center, Charlottesville, VA. Best Practice & Research Clinical Anaesthesiology, Vol. 22, No. 3, pp. 537-552, 2008.
8. *"The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?"*. J KC Huang, et al. Queen Elizabeth Hospital, King's Lynn, UK. *Critical Care* 2003, 7:R13-R16. 4 March 2003.
9. *"Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room"*. R. S. Zink & P. A. Iaizzo. University of Minnesota, Minneapolis, MN. ANESTHESIA & ANALGESIA, Vol. 76, No. 1, January 1993.
10. *"Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room"*. A.C. Hall, MB, MS; T. Teenier, DDS. University of Texas Southwestern Medical Center, Dallas, TX. Poster Presentation, PGA, 9 December 1991.
11. *"Convection warmers- a possible source of contamination in laminar airflow operating theatres?"*. N Tumia and G. P. Ashcroft. Aberdeen University Medical School, Foresterhill, Aberdeen, Scotland. Journal of Hospital Infection (2002) 52: 171-174.
12. *"Forced-Air Warmer Did Not Increase the Risk of Contamination Caused by Interference of Clean Airflow"*. H Miyazaki, MD, et al. Anesthesiology 2007; 107: A1594.
13. Bair Hugger Complaints from January 2006-present on CD-ROM
14. Bair Paws and Ranger Complaints from January 2006-present on CD-ROM
15. SOP 140201 Recall and Advisory Notice Procedure, Rev E
16. Power Cord recall letter sent to MIN-DO 12/07/09

17. "Urgent: Medical Device Power Cord Recall" letter dated 12/2009
18. SOP 140500 Adverse Event/Injury Reporting , Rev G
19. Letter addressed to U.S. Food and Drug Administration dated May 7, 1992
20. CALL 63505 dated 04/13/06
21. CALL 73378 dated 07/30/07
22. CALL 76774 dated 01/02/08
23. CALL 92646 dated 08/29/09
24. CALL 66624 dated 09/14/06
25. CALL 81669 dated 07/15/08
26. CALL 90142 dated 05/22/09
27. CALL 79475 dated 04/16/08
28. CALL 95129 dated 11/09/09
29. CALL 85323 dated 11/25/08
30. Consignee list from January 2007 Model 850 Service Bulletin
31. Model 850 Service Bulletin
32. Blower Instructions included as part of Service Bulletin
33. SOP 140400, Complaint Management, Rev L
34. CALL 85743 dated 12/12/08
35. CALL 89918 dated 05/13/09
36. CALL 90025 dated 05/19/09
37. CALL 91168 dated 06/30/09
38. CALL 91451 dated 07/10/09
39. CALL 95193 dated 11/11/09
40. Corrective Action Request Document #1247

ATTACHMENTS

1. Copy of Assignment from CDHR
2. FDA-482, Notice of Inspection, issued to David A. Westlin dated 11/30/2009
3. FDA-483, Inspectional Observations, issued to Gary R. Maharaj dated 01/06/2010
4. Recommendation for Recall Classification Memo dated 01/12/10

Jessica L. Johnson

Jessica L. Johnson, Investigator